

DEPARTMENT OF THE AIR FORCE 59TH MEDICAL WING (AETC) JOINT BASE SAN ANTONIO - LACKLAND TEXAS



16 MAR 2017

MEMORANDUM FOR SGOM5E

ATTN: LT COL IRENE FOLARON

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

- Your paper, entitled <u>Diabetes in Combat: Effect of Military Deployment on Diabetes Mellitus in Air Force Personnel</u> presented at/published to <u>American Diabetes Association</u>, <u>Orlando</u>, <u>FL</u>, 1 <u>April 2017 & San Antonio Uniformed Services Research Symposium</u>, <u>San Antonio</u>, <u>TX</u>, 16 <u>April 2017</u> in accordance with MDWI 41-108, has been approved and assigned local file #17149.
- 2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
- 3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.
- 4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC Director, Clinical Investigation & Research Support

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PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

- 1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D;
 Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed
 Medical Research Program (CDMRP); Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
- 2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
- Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
- 4. Attach a copy of your abstract, paper, poster and other supporting documentation.
- 5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
- 6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
- 7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). This should be accomplished no later than 30 days before final clearance is required to publish/present your materials. If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
- 8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
- Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. Note: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
- 10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, Presentation and Publication of Medical and Technical Papers, for additional information.
- 11. The Joint Ethics Regulation (JER) DoD 5500.07-R, Standards of Conduct, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review. To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

- NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:
 - "The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"
- NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:
 - "The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."
- NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN
 - "The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS									
1. TO: CLINICAL RESEARCH 2. FROM: (Author)	or's Name, Rank, Grade, Office Symbol) 3. GME					4. PROTOCOL NUMBER:			
Folaron, Irene,	Lt Col, O-5, SGOM5E	E		YES	⊠ NO	FWH20160079H			
5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039									
must be submitted for review and approval.) Effect of Military Deployment on Diabetes Mellitus in Active Duty Air Force Personnel									
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:									
Diabetes in Combat: Effect of Military Deployment on Diabetes Mellitus in Air Force Personnel									
7. FUNDING RECEIVED FOR THIS STUDY? YES NO FUNDING SOURCE:									
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: X YES NO									
9. IS THIS MATERIAL CLASSIFIED? YES NO									
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? YES NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.									
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CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED. 11a. PUBLICATION/JOURNAL (List intended publication/journal.)									
11b. PUBLISHED ABSTRACT (List intended journal.)									
LI TID. PUBLISHED ABSTRACT (LISTINGENDED JOURNAL)									
11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.) American Diabetes Association, Orlando, FL, 4/1/17; San Antonio Uniformed Services Research Symposium, San Antonio, 4/16/17									
11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meting.)									
11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)									
12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED?									
☐ YES ☐ NO ASSIGNED FILE # DATE									
13. EXPECTED DATE WHEN YOU WILL NEED NOTE: All publications/presentations are re	THE CRD TO SUBMIT quired to be placed in the	YOUR CL e Defense	EARED PRESENTA Technical Information	ATION/PUBLIC on Center (DT	CATION TO D	OTIC			
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A. Primary/Corresponding Author Folaron, Irene	O-5 Lt Col	959th N	959th MDOS/959th MDG						
b. Wardian, Jana L	CTR		959th MDSP/959th MDOG						
c. True, Mark W	O-6, Col		959th MDOS/959th MDG						
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17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? YES NO I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR									
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21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Mark W. True, Col, Chief of Research, Dept of Medicine				AUTHORITY'S SIGNATURE 23. DATE 2949757 Interpretation of the property of the p		[[] [] [] [] [] [] [] [] [] [

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS								
1st ENDORSEMENT (59 MDW/SGVU Use Only)								
TO: Clinical Research Division	24. DATE RECEIVED		25. ASSIGNED PROCESSING REQUEST FILE NU	IMBER				
59 MDW/CRD Contact 292-7141 for email instructions.	March 09, 2017		17149					
26. DATE REVIEWED		2	27. DATE FORWARDED TO 502 ISG/JAC					
March 14, 2017								
28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: NO YES If yes, give date.								
29. COMMENTS APPROVED DISAPPROVED								
IRB approved research presentation wit	h appropriate disclosures.	appro	ved					
30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER			31. REVIEWER SIGNATURE 32. DATE					
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41. COMMENTS APPROVED (In compliance with security and policy review directives.)								
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Diabetes in Combat: Effect of Military Deployment on Diabetes Mellitus in Air Force Personnel

Irene Folaron¹, Jana L. Wardian², Mark W. True¹, Tom J. Sauerwein²

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²Diabetes Center of Excellence, Wilford Hall Medical Center, Lackland Air Force Base, TX

The United States Air Force (USAF) restricts military personnel with Diabetes Mellitus (DM) from participating in military deployments due to the uncertainty of healthcare availability in an austere environment. For military providers, assessing a member's candidacy for deployment has been challenging as no data has been published describing the effect of a deployment on glycemic control among military personnel with DM.

We conducted a retrospective analysis on 366 USAF personnel with DM examining response in hemoglobin A1C (A1C) and body mass index (BMI) after a deployment of at least 90 days. Each subject's A1C and BMI were obtained before deployment and within 6 months of repatriation. For the entire population, there was no statistically significant difference in the mean A1C before and after deployment (6.5% vs. 6.7% respectively, P=0.17). Likewise, subgroup analyses of gender, rank, and age showed no significant difference in A1C before and after deployment. In subjects taking oral DM medications only or no medications, which represent the ideal regimen in deployment due to cold storage limitations, there was no significant difference in A1C before and after deployment (n=335, 6.4% vs. 6.6% respectively, P=0.09). However, members requiring insulin appeared to have worsened glycemic control before and after deployment (A1C 7.8% vs. 8.4%, respectively), although the census in this category (n=25) was insufficient to accurately calculate statistical significance. Mean BMI for the overall population declined significantly after deployment (28.4kg/m² vs. 27.8kg/m², P<0.01).

A1C appears to remain relatively stable before and after a deployment among AF personnel with DM. However, those requiring insulin demonstrated a concerning pattern of A1C increase. Further studies are needed to determine specific factors in military deployment that affect glycemic control.

The views expressed are those of the author and do not reflect the official views of policy of the Department of Defense or its Components.

DIABETES IN COMBAT: EFFECT OF MILITARY DEPLOYMENT ON DIABETES MELLITUS IN AIR FORCE PERSONNEL

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Background:

The United States Air Force (USAF) restricts military personnel with Diabetes Mellitus (DM) from participating in military deployments due to the uncertainty of healthcare availability in an austere environment. For military providers, it has been challenging to assess the deployment candidacy of a member with DM since no data has been published to date describing the effect of a deployment on glycemic control. We conducted a retrospective analysis on USAF personnel who deployed with DM to examine their response in hemoglobin A1C (A1C) and body mass index (BMI) after a deployment of at least 90 days.

Methods:

Subjects were identified by ICD-9 diagnosis of Diabetes Mellitus through the Department of Defense electronic health record. A1C and BMI were also gathered through the electronic health record. Deployment information was obtained through the Aerospace Information Management System. Medication information at the time of deployment with obtained through the Pharmacy Data Transaction Service database. All databases are maintained by the Defense Health Agency.

Results:

We identified 366 USAF personnel who deployed with a diagnosis of DM between 2004 and 2014. Each subject's A1C and BMI were obtained before deployment and within 6 months of repatriation. For the entire population, there was no statistically significant difference in the mean A1C before and after deployment (6.5% vs. 6.7% respectively, *P*=0.17). Likewise, subgroup analyses of gender, rank, and age showed no significant difference in A1C before and after deployment. In subjects taking oral DM medications only or no medications, which represent the ideal regimen in deployment due to cold storage limitations, there was no significant difference in A1C before and after deployment (n=335, 6.4% vs. 6.6% respectively, *P*=0.09). However, members requiring insulin appeared to have worsened glycemic control before and after deployment (A1C 7.8% vs. 8.4%, respectively), although the census in this category (n=25) was insufficient to accurately calculate statistical significance. Mean BMI for the overall population declined significantly after deployment (28.4kg/m² vs. 27.8kg/m², *P*<0.01).

Conclusion:

A1C appears to remain relatively stable before and after a deployment among AF personnel with DM. However, those requiring insulin demonstrated a concerning

pattern of A1C increase. Further studies are needed to determine specific factors in military deployment that affect glycemic control.

Acknowledgements: Dr. Alan Sim, Ms. LeeAnn Zarzabal, and Mr. Alexander Rittel of the Defense Health Agency for assistance with data acquisition.

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